UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

DATE MAILED: 02/28/2008

# NOTICE OF ALLOWANCE AND FEE(S) DUE

23117 7590 0228/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203

| EXAMINER            |              |  |  |
|---------------------|--------------|--|--|
| RAGHU, GANAPATHIRAM |              |  |  |
| ART UNIT            | PAPER NUMBER |  |  |
| 1652                | •            |  |  |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/539,834      | 01/30/2006  | Hisashi Narimatsu    | GRT/159-89          | 5006             |

TITLE OF INVENTION; GLYCOS YLTRANSFERASE, NUCLEIC ACID ENCODING THE GLYCOS YLTRANSFERASE AND METHOD OF TESTING CANCERATION USING THE NUCLEIC ACID

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO           | \$1440        | \$300               | \$0                  | \$1740           | 05/28/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

| INSTRUCTIONS: This<br>appropriate. All further c<br>indicated unless correcte<br>maintenance fee notificat   | form should be used to<br>correspondence including<br>d below or directed oth<br>ions.   | for transmitting the ISS<br>ig the Patent, advance<br>nerwise in Block 1, by                                 | SUE FEE and PUBLICATI<br>orders and notification of r<br>(a) specifying a new corres   | ON FEE (if require<br>naintenance fees will<br>pondence address; a  | <ul> <li>d). Blocks 1 through 5 s</li> <li>l be mailed to the current<br/>nd/or (b) indicating a sep</li> </ul>                               | should be completed where<br>correspondence address a<br>arate "FEE ADDRESS" fo   |
|--|--|--|--|---|---|---|
|  |  | iock 1 for any change of address   | Feet   | s) Transmittal. This or<br>rs. Each additional p  | ailing can only be used for<br>certificate cannot be used a<br>saper, such as an assignment<br>f mailing or transmission.                     | or domestic mailings of the<br>for any other accompanying<br>ent or formal drawing, must  |
| NIXON & VAN  | EBE ROAD, 11TH   |  | I be   | Certify   | icate of Mailing or Trans   | smission<br>g deposited with the United<br>st class mail in an envelope<br>above, or being facsimile<br>late indicated below.                     |
|  |  |  |  |   |   | (Depositor's name)  |
|  |  |  |  |   |   | (Signature)   |
|  |  |  |  |   |   | (Date)  |
| APPLICATION NO.  | FILING DATE  |  | FIRST NAMED INVENTOR   | Α   | TTORNEY DOCKET NO.  | CONFIRMATION NO.  |
| 10/539,834   | 01/30/2006   |  | Hisashi Narimatsu  | •   | GRT/159-89  | 5006  |
| TITLE OF INVENTION:<br>CANCERATION USING   |  |  | TO ENCODING THE GLY  | COSYLTRANSFER   | ASE AND METHOD OF   | TESTING   |
| APPLN. TYPE  | SMALL ENTITY   | ISSUE FEE DUE  | PUBLICATION FEE DUE  | PREV. PAID ISSUE I  | EE TOTAL FEE(S) DUE   | DATE DUE  |
| nonprovisional   | NO   | \$1440   | \$300  | \$0   | \$1740  | 05/28/2008  |
| EXAMI  | NER  | ART UNIT   | CLASS-SUBCLASS   |   |   |   |
| RAGHU, GANA  | APATHIRAM  | 1652   | 435-097000   |   |   |   |
| "Fee Address" indi<br>PTO/SB/47; Rev 03-0/<br>Number is required.  3. ASSIGNEE NAME AN<br>PLEASE NOTE: Unle<br>recordation as set forth                                    | ondence address (or Cha<br>v122) attached.<br>cation (or "Fee Address<br>2 or more recent) attach<br>ND RESIDENCE DATA<br>ess an assignee is ident<br>in 37 CFR 3.11. Comp | inge of Correspondence  " Indication form and. Use of a Customer  A TO BE PRINTED ON                         | THE PATENT (print or type<br>e data will appear on the p<br>OT a substitute for filing an  | rely,  e firm (having as a magent) and the names meys or agents. If no printed.  ec)  atent. If an assignce assignment. | sember a 2of up to name is 3is identified below, the c  | locument has been filed for   |
| Please check the appropri-   | ate assignee category or<br>are submitted:   |  | 4b. Payment of Fee(s): (Plea   | Individual Corp   | oration or other private gr   | oup entity Government   |
| Advance Order - #  | o small entity discount p  | permitted)   | Payment by credit car The Director is hereby overpayment, to Depo  | authorized to charge  | the required fee(s), any de   | eficiency, or credit any<br>an extra copy of this form).  |
|  | SMALL ENTITY state   | as. See 37 CFR 1.27.   |  |   | ENTITY status. Sec 37 C   |   |
| interest as shown by the n   | l Publication Fee (if requeeords of the United Sta   | uired) will not be accept<br>ites Patent and Tradema   | ted from anyone other than t<br>rk Office.   | he applicant; a registe   | ered attorney or agent; or t  | he assignee or other party in   |
| Authorized Signature   |  |  |  | Date  |   |   |
| Typed or printed name  |  |  |  | Registration No.  |   |   |
| This collection of informs<br>an application. Confident<br>submitting the completed<br>this form and/or suggestic<br>Box 1450, Alexandria, Vi<br>Alexandria, Virginia 2231 | ation is required by 37 C<br>iality is governed by 35<br>application form to the<br>ons for reducing this but<br>reginia 22313-1450. DC<br>(3-1450.                        | CFR 1.311. The informate U.S.C. 122 and 37 CFI USPTO. Time will varien, should be sent to a NOT SEND FEES OF | tion is required to obtain or r<br>R 1.14. This collection is est<br>ry depending upon the indiv<br>the Chief Information Office<br>R COMPLETED FORMS TO | etain a benefit by the<br>imated to take 12 min<br>idual case. Any com<br>r, U.S. Patent and Tr<br>D THIS ADDRESS.      | public which is to file (an<br>nutes to complete, including<br>ments on the amount of ti<br>ademark Office, U.S. Dep<br>SEND TO: Commissioner | d by the USPTO to process<br>ag gathering, preparing, and<br>me you require to complete<br>artment of Commerce, P.O<br>for Patents, P.O. Box 1450 |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010. OMB 0651-0033



# UNITED STATES PATENT AND TRADEMARK OFFICE

#### UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/539,834 01/30/2006                                   |             | Hisashi Narimatsu    | GRT/159-89 5006     |                  |
| 23117 7590 02/28/2008                                   |             |                      | EXAMINER            |                  |
| NIXON & VANDERHYE, PC                                   |             | RAGHU, GAN           | APATHIRAM           |                  |
| 901 NORTH GLEBE ROAD, 11TH FLOOR<br>ARLINGTON, VA 22203 |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1652                |                  |

DATE MAILED: 02/28/2008

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

| Application No.     | Applicant(s)     |  |
|---------------------|------------------|--|
| 10/539,834          | NARIMATSU ET AL. |  |
| Examiner            | Art Unit         |  |
| GANAPATHIRAMA RAGHU | 1652             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addressAll claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to 01/23/08.
- 2. The allowed claim(s) is/are 13,14 and 31-34.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) 

    All b) 

    Some\* c) 

    None of the:
    - 1. A Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
    - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDOMMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) Thereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

 DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. 
  Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08),
- Paper No./Mail Date <u>See Continuation Sheet</u>

  4. Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- Other .

 $Continuation \ of \ Attachment(s) \ 3. \ Information \ Disclosure \ Statements \ (PTO/SB/08), \ Paper \ No./Mail \ Date: \ 06/17/05; \ 10/11/05; \ 10/11/06; \ 1$ 

#### Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/23/08 has been entered.

In response to the Final Office Action on 07/23/2007 applicants' filed a response received on 01/23/08. Said response amended claims 13, 14, 24 and added new claims 31-34. Thus, claims 13, 14, 24 and 31-34 are pending in the instant Office Action and are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Claims 14, 33 and 34 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 13, 24, 31 and 32 directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, 04/16/2007 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 06/01/2006 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory

Application/Control Number: 10/539,834

Art Unit: 1652

double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPO 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 of PCT/JP03/17030, filed on 12/26/2003 and claims priority to Japanese Application JAPAN 2002-38075 filed on 12/27/2002 and a certified copy of English translation has been provided on 01/23/08 for the Japanese Application 2002-38075.

## Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/17/05, 10/11/05 and 10/11/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the IDS statement.

### EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Gary Tanigawa on 02/20/2008. Art Unit: 1652

The application has been amended as follows:

#### In the Claims

Please replace the claims with the marked-up set of claims provided by the applicants' representative Gary Tanigawa on 02/20/2008 and attached herein along with the action

# Allowable Subject Matter

Claims 13, 14 and 31-34 are allowed.

The following is an examiner's statement of reasons for allowance: Following a diligent search it was determined that the prior art neither teaches nor suggests an isolated polypeptide of SEQ ID NO: 2 or SEQ ID NO: 16 with  $\beta$ 1,3-N-acetyl-D-glucosaminyltransferase activity. The closest prior art to SEQ ID NO: 2 or 16 of the instant application is Conklin et al., (US Patent No.: 6416988), discloses polynucleotides and encoding polypeptides having 99.8% sequence homology to SEQ ID NO: 2 and 16 of the instant invention. The polypeptides of the instant invention differ from the prior art wherein SEQ ID NO: 2 has an amino acid residue "S" at position 137 and SEQ ID NO: 16 has an amino acid residue "S" at position 112. The isolated polypeptides with SEQ ID NO: 2 or 16 of the instant application appears to be a natural single nucleotide polymorphism (SNP) of a gene encoding  $\beta$ 1,3-N-acetyl-D-glucosaminyltransferase activity and therefore would not have been obvious to one skilled in the art to change/mutate the specific amino acid residues as reported for SEQ ID NO: 2 or 16.

Any comments considered necessary by applicant must be submitted no later than the payment of issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Application/Control Number: 10/539,834 Page 5

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D. Patent Examiner Art Unit 1652 Feb. 08, 2008.

/Rebecca E. Prouty/ Primary Examiner, Art Unit 1652